K003790

DEC 22 2000

7.0 510(k) Summary of Safety and Effectiveness Information:

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A) Submitter Information:

Submitter's Name:	Lucinda L. Fox
Address:	Davol Inc. 100 Sockanossett Crossroad Cranston, Rhode Island 02920
Phone Number:	(401) 463-7000
Fax Number:	(401) 463-3845
Contact Person:	Lucinda L. Fox
Date of preparation:	November 10, 2000

B) Device Name:

Trade Name:	Davol® X-Stream™ Laparoscopic Irrigation System
Common/Usual Name:	Laparoscopic Irrigator
Classification Name:	Laparoscope, General & Plastic Surgery

C) Predicate Product:

HydroFlex™ LI Laparoscopic Irrigation System (K961224)

The Davol® X-Stream™ Laparoscopic Irrigation System (**X-Stream** System) proposed in this submission is substantially equivalent to Davol's currently marketed HydroFlex™ LI Laparoscopic Irrigation System (K961224). Both devices are designed to provide controlled irrigation to

the operative site during laparoscopic procedures and. Both devices include a Disposable Bowl or Pumping Chamber/Tubing Set and a reusable Controller.

C) Description and Intended Use:

The Davol® X-Stream™ Laparoscopic Irrigation System (**X-Stream** System) is designed to provide controlled irrigation to the operative site during laparoscopic procedures. The system helps flush blood and tissue debris from the operative site during laparoscopy to aid visualization. It may also be useful for resection of filmy adhesions (hydrodissection), hydrodissolution of blood clots and peritoneal lavage.

The **X-Stream** System is an electrically powered, centrifugal pump system designed to provide controlled irrigation to the operative site during laparoscopic procedures. It consists of a reusable Controller and a disposable Pumping Chamber/Tubing set. It will be provided pre-attached to a variety of laparoscopic trumpet-valve style handpieces and may include probe tips currently marketed by Davol. The different configurations of Trumpet-Valve handpieces, with/without smoke evacuation capability, are currently marketed by Davol, all of which were cleared through the premarket notification (Section 510(k)) process. In addition, some of the pre-attached Trumpet-Valve handpieces will include a quick-disconnect feature to allow the user to attach other Davol marketed laparoscopic probe tips (irrigation/aspiration, electrosurgical irrigation/ aspiration, and irrigation/ aspiration with laser channel).

Once the Pumping Chamber is properly seated in the Controller and the system has been primed (e.g., fluid has filled the pumping chamber and activated the Flow Switch), fluid flow is initiated by depressing the irrigation button on the Trumpet-Valve handpiece. The Controller operates in two modes, Default and Maximum; however, it activates in the Default mode. The user can toggle between Default and Maximum to control the fluid flow rate. Rate of flow is dependent on the Controller setting, Trumpet-Valve irrigation button depression, and probe tip selection.

A) Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

A comparison chart is provided summarizing the similarities and differences in intended use, design, and performance between the two systems (reference Attachment 1 to this Section). The 510(k) "Substantial Equivalence Decision Making Process (Detailed)" decision tree was utilized to make a determination of substantial equivalence.

1) Does the New Device Have the Same Indication Statement?

Yes. The **X-Stream** System and the **HydroFlex** LI Laparoscopic Irrigation System are intended to provide controlled irrigation during laparoscopic procedures. The devices flush blood and tissue debris from the operative site during laparoscopy to aid in visualization and may also be useful for resection of filmy adhesions (hydrodissection), hydrodissolution of blood clots and peritoneal lavage.

2) Does the New Device have the same Technological Characteristics, e.g., Design, Materials, etc.?

No. Although the **X-Stream** System and the **HydroFlex** LI Laparoscopic Irrigation System (**HydroFlex** LI System) have the same basic components (Controller, Disposable, Inflow Tubing, Outflow Tubing), the design of these components may vary as well as the principle of operation.

Although both are electromechanical Systems involving an impeller pump driven by a Controller, their configurations and principles of operation are different. The **HydroFlex** LI System has a multi-application electronic Controller whereas the **X-Stream**

System has a single application, electronic Controller. The **HydroFlex** Controller is such that it can be used as a multi-purpose fluid irrigation system (depending on the disposable Pump Tubing Set used with the Controller); however, the **HydroFlex** LI System is indicated for laparoscopic irrigation use only. The **X-Stream** System's reusable, single-application Controller can only be used with the **X-Stream** Pumping Chamber/Tubing Set for laparoscopic use.

Fluid input pressure for the **HydroFlex** LI System is determined by the selected input pressure setting on the Controller and may be adjusted as needed to increase/decrease the flow rate of irrigant. Its selectable operational range is between 70 to 500 (mmHg). However, instead of a selectable range, the **X-Stream** System has two settings, Default and Maximum. In the **HydroFlex** LI System, the motor runs continuously, which spins the impeller throughout the procedure. For the **X-Stream** System, the motor runs intermittently depending on the activation of the Flow Switch (PCB in conjunction with the IR pair and position of the Float Ball within the Float Ball Chamber). Therefore, the impeller only turns when the motor is running. Both Systems include Trumpet-Valve handpieces that allow the user variable control over irrigant delivery to the operative site.

3) **Could the New Characteristics Affect Safety or Effectiveness.**

Yes. The change in operation principle used in the **X-Stream** System (Flow Switch) could affect the effectiveness of the irrigation device's ability to provide an adequate flow rate for laparoscopic procedures.

The use of different fluid contact materials in the **X-Stream** System could affect the safe and effective use of the system if the materials were not biocompatible.

The responses to questions 5 and 6 below address the assessment of the affects of the new characteristics on the safety or effectiveness.

4) Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?

Yes. The assessment of characteristics of a laparoscopic irrigation system (adequate flow rates) can be performed by utilizing relatively simple experimental methods. In addition, there are electromechanical standards available for assessing electrical devices. The **X-Stream** System's reusable Controller will be compliant with applicable sections of UL 2601-1 (MEE Safety), IEC 60601-1 (MEE Safety) and IEC 60601-1-2 (EMC).

There are well accepted tests available for assessing the biocompatibility of new materials for use in medical devices.

5) Are Performance Data Available to Assess the Effects of the New Characteristics?

Yes. Laboratory bench testing has been performed to assess the effects of the new characteristics of the **X-Stream** System as compared to the **HydroFlex** LI System. This testing involved the measurement of flow rate from both systems at maximum settings and included a trumpet-valve handpiece and a suction/irrigation probe. In addition, there are electromechanical standards available for assessing electrical devices. The **X-Stream** System's reusable Controller will be compliant with applicable sections of UL 2601-1 (MEE Safety), IEC 60601-1 (MEE Safety) and IEC 60601-1-2 (EMC).

Biocompatibility testing, performed in accordance with the FDA General Program Memorandum #G-95-1 has been conducted on all materials utilized in the fluid path of the **X-Stream** System.

6) **Does Performance Data Demonstrate Equivalence?**

Yes. Based upon the results of the laboratory testing, the **X-Stream** System compares favorably with the **HydroFlex** LI System in regards to the devices' ability to provide controlled irrigation to an operative site during laparoscopic procedures. Results from the biocompatibility testing have show that the materials used for the manufacture of the Disposable part of the **X-Stream** System are suitable for externally communicating devices with limited duration tissue contact.

CONCLUSION:

Based upon the above information, the **Davol X-Stream** Laparoscopic Irrigation System is substantially equivalent to the **Davol HydroFlex** LI Laparoscopic Irrigation System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2001

Davol, Inc.
c/o Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

Re: K003790
Trade Name: Davol X-Stream Laparoscopic Irrigation System
Regulatory Class: II
Product Code: GCJ, HET
Dated: December 7, 2000
Received: December 8, 2000

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of December 21, 2000 regarding the Product Code.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: Unknown K003790

Device Name: Davol® X-Stream™ Laparoscopic Irrigation System

Indications for Use:

The Davol® X-Stream™ Laparoscopic Irrigation System is designed to provide controlled irrigation to the operative site during laparoscopic procedures. The system helps flush blood and tissue debris from the operative site during laparoscopy to aid visualization. It may also be useful for resection of filmy adhesions (hydrodissection), hydrodissolution of blood clots and peritoneal lavage.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 003790

Prescription Use ✓ Or Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)